

## § 349.10

causes transient constriction of conjunctival blood vessels.

### Subpart B—Active Ingredients

#### § 349.10 Ophthalmic astringent.

The active ingredient and its concentration in the product is as follows: Zinc sulfate, 0.25 percent.

#### § 349.12 Ophthalmic demulcents.

The active ingredients of the product consist of any of the following, within the established concentrations for each ingredient:

- (a) Cellulose derivatives:
  - (1) Carboxymethylcellulose sodium, 0.2 to 2.5 percent.
  - (2) Hydroxyethyl cellulose, 0.2 to 2.5 percent.
  - (3) Hydroxypropyl methylcellulose, 0.2 to 2.5 percent.
  - (4) Methylcellulose, 0.2 to 2.5 percent.
- (b) Dextran 70, 0.1 percent when used with another polymeric demulcent agent in this section.
- (c) Gelatin, 0.01 percent.
- (d) Polyols, liquid:
  - (1) Glycerin, 0.2 to 1 percent.
  - (2) Polyethylene glycol 300, 0.2 to 1 percent.
  - (3) Polyethylene glycol 400, 0.2 to 1 percent.
  - (4) Polysorbate 80, 0.2 to 1 percent.
  - (5) Propylene glycol, 0.2 to 1 percent.
  - (e) Polyvinyl alcohol, 0.1 to 4 percent.
  - (f) Povidone, 0.1 to 2 percent.

#### § 349.14 Ophthalmic emollients.

The active ingredients of the product consist of any of the following:

- (a) Lanolin preparations:
  - (1) Anhydrous lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.
  - (2) Lanolin, 1 to 10 percent in combination with one or more oleaginous emollient agents included in the monograph.
- (b) Oleaginous ingredients:
  - (1) Light mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.
  - (2) Mineral oil, up to 50 percent in combination with one or more other emollient agents included in the monograph.

## 21 CFR Ch. I (4–1–03 Edition)

(3) Paraffin, up to 5 percent in combination with one or more other emollient agents included in the monograph.

- (4) Petrolatum, up to 100 percent.
- (5) White ointment, up to 100 percent.
- (6) White petrolatum, up to 100 percent.

(7) White wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.

(8) Yellow wax, up to 5 percent in combination with one or more other emollient agents included in the monograph.

#### § 349.16 Ophthalmic hypertonicity agent.

The active ingredient and its concentration in the product is as follows: Sodium chloride, 2 to 5 percent.

#### § 349.18 Ophthalmic vasoconstrictors.

The active ingredient of the product consists of one of the following, within the established concentration for each ingredient:

- (a) Ephedrine hydrochloride, 0.123 percent.
- (b) Naphazoline hydrochloride, 0.01 to 0.03 percent.
- (c) Phenylephrine hydrochloride, 0.08 to 0.2 percent.
- (d) Tetrahydrozoline hydrochloride, 0.01 to 0.05 percent.

#### § 349.20 Eyewashes.

The active ingredient of the product is purified water. The product also contains suitable tonicity agents to establish isotonicity with tears, suitable agents for establishing pH and buffering to achieve the same pH as tears, and a suitable preservative agent.

[68 FR 7921, Feb. 19, 2003]

#### § 349.30 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established concentration, and the product is labeled in accordance with § 349.79.

- (a) Any single ophthalmic astringent active ingredient identified in § 349.10